

K072937

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510 (k) Summary
Olsen Medical Integrated Irrigation Tubing and Bipolar Cord Set

Company Name and Address:

Olsen Medical
3001 West Kentucky Street
Louisville, KY 40211
Phone (502) 772-4280
Fax (502) 772-4282

DEC 28 2007

Contact Information:

John Waters
Director of Quality & Regulatory Affairs
Olsen Medical
3001 West Kentucky Street
Louisville, KY
Telephone (502) 772-4280
Facsimile (502) 772-4282
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Device Classification:

Electrosurgical Cutting and Coagulation Device & Accessories are Class II devices per 21 CFR 878.4400

Statement of Substantial Equivalence:

Olsen Medical Integrated Irrigation Tubing & Bipolar Cord Sets are substantially equivalent to Codman's Integrated Irrigation Tubing and Bipolar Cord Set (K052449) based on the device's similarity to the predicated device in intended use, materials, design, and functionality.

Indications for Use:

The OLSEN MEDICAL Integrated Irrigation Tubing and Bipolar Cord Set (Catalog No. 40-3xxx) is a single use product sold sterile and is intended for use with a standard bipolar irrigating forceps like the OLSEN MEDICAL Bipolar Irrigating Forceps and the Codman & Shurtleff, Malis™ CMC® Bipolar Systems to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation. This device is intended for use with the Codman/Malis™ CMC®-II and the CODMAN/MALIS™ CMC®-III

Bipolar Cut and Coagulation System (or equivalent) Electrosurgical Generator.

Bipolar forceps specifically designed for irrigating are required for use with this tubing and cord set. Please read the instruction manuals supplied with the irrigation module and the bipolar coagulator or electrosurgical systems before using this product.

Description:

The OLSEN MEDICAL Integrated Irrigation Tubing and Bipolar Cord Set is packaged sterile with a nonpyrogenic fluid pathway. It consists of inlet spike with protective cap, and on/off clamp silicone tubing and fittings, a male LUER-LOK™ connector, two plugs and a female twin-pin socket connector. A co-extrusion process integrates a single use bipolar cord with irrigation tubing set. This integrated set provides the system with one unit delivery conduit and cable for carrying irrigating solution and electrosurgical energy to the Bipolar Irrigation Forceps for coagulation and irrigation of selected tissue.

Device Testing:

The new device is technologically the same as the predicate device. Device qualification criteria meet or exceed the minimum qualification criteria for the predicate device. The device conforms to applicable ASTM and ISO Standards. Tests will meet the applicable requirements of ANSI/AAMI HF18:2001 and IEC 60601-2-2 3rd Edition.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

DEC 28 2007

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Olsen Medical
% Mr. John P. Waters
Director of Quality and
Regulatory Affairs
3001 West Kentucky Street
Louisville, Kentucky 40211

Re: K072937

Trade/Device Name: Olsen Medical Integrated Irrigation Tubing and Bipolar Cord Set
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 12, 2007
Received: December 17, 2007

Dear Mr. Waters:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Indications for Use

510(k) Number (if known):

Device Name: Olsen Medical Integrated Irrigation Tubing and Bipolar Cord Set

Indications For Use:

The OLSEN MEDICAL Integrated Irrigation Tubing and Bipolar Cord Set (Catalog No. 40-3xxx) is a single use product sold sterile and is intended for use with a standard bipolar irrigating forceps like the OLSEN MEDICAL Bipolar Irrigating Forceps and the Codman & Shurtleff, Malis™ CMC® Bipolar Systems to provide irrigation and energy simultaneously to bipolar forceps specifically designed for irrigation. This device is intended for use with the Codman/Malis™ CMC® -II and the CODMAN/MALIS™ CMC®-III Bipolar Cut and Coagulation System (or equivalent) Electrosurgical Generator.

Bipolar forceps specifically designed for irrigating are required for use with this tubing and cord set. Please read the instruction manuals supplied with the irrigation module and the bipolar coagulator or electrosurgical systems before using this product.

Prescription Use ☒
(21 CFR Part 801 Subpart D)

And/Or

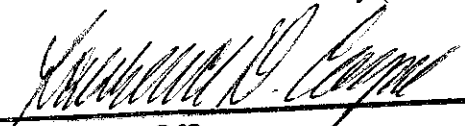
Over the Counter Use ☐
(21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____



(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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